

## PATENT ATTORNEY DOCKET NO. 01997/518004

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Seth Eckstein

Printed name of person mailing correspondence

Selbelat

Signature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Mikos et al.

Confirmation No.:

8716

Serial No.:

10/775,768

Art Unit:

1651

Filed:

February 10, 2004

Examiner:

David M. Naff

Customer No.:

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL

TRANSPLANTATION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### REQUEST TO CORRECT INVENTORSHIP UNDER 37 C.F.R. § 1.48 (a)

Applicant hereby requests correction of inventorship in the above-captioned application from:

Antonios G. Mikos, Donald E. Ingber, Joseph P. Vacanti, and Robert S. Langer

Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith, and Georgios Sarakinos.

Linda G. Griffith is formerly named Linda G. Cima.

The inventors set forth in the executed Declaration under 37 C.F.R. § 1.63 that was filed in this case on August 31, 2004 were in error. In support of this request, enclosed

to:

are:

A statement from each person being added as an inventor (Griffith and Sarakinos) and the person being removed as an inventor (Ingber) that the error in inventorship occurred without deceptive intent, filed in U.S. Patent No. 6,689,608, formerly U.S. Application Serial No. 09/669,760 (Exhibits A-C).

Executed Declarations filed in U.S. Patent No. 6,689,608, formerly U.S. Application Serial No. 09/669,760, under 37 C.F.R. § 1.63 by the actual inventors (Exhibits D-H).

A check for \$130.00 for the fee required under 37 C.F.R. § 1.17(i).

A written consent of the assignee to this correction of inventorship, filed in U.S. Patent No. 6,689,608, formerly U.S. Application Serial No. 09/669,760 (Exhibits I and J).

A Request to Correct Inventorship under 37 C.F.R. § 1.48(a), filed in U.S. Patent No. 6,689,608, formerly U.S. Application Serial No. 09/669,760 (Exhibit K).

The above-referenced documents, submitted herewith, were originally submitted in the parent case Mikos et al. (U.S. Patent No. 6,689,608; hereafter "Mikos '608", formerly U.S. Application Serial No. 09/669,760) of the present application (U.S. Application Serial No. 10/775,768), a continuation of U.S. Application Serial No. 09/669,760, was and should be applied for the reasons detailed below to the present application.

#### Prosecution History

An incorrect Declaration was filed in the present case on August 31, 2004 (Exhibit L) in response to a Notice to File Missing Parts of Nonprovisional Application mailed on May 6, 2004 (Exhibit M). As a result of the August 31, 2004 Declaration being filed instead of the corrected Declaration, the inventorship of the present application was changed from the correct inventors "Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith, and Georgios Sarakinos," as noted on the original cover sheet of the present application filed February 10, 2004 (Exhibit N), to "Antonios G. Mikos, Donald E. Ingber, Joseph P. Vacanti, and Robert S. Langer" as noted on the second filing receipt mailed on March 21, 2006 (Exhibit O).

#### Reasons for Correction

As an initial matter, Applicants note that the disclosure of the present application is identical to that of the Mikos '608 application. In addition, we note that the Office has identified the subject matter of the independent claim of the present application as identical to the subject matter of the independent claim of its parent application through a Statutory-Type Double Patenting rejection (page 3 of Exhibit P). The correct inventors' Declarations extend to "the subject matter described and claimed" in the parent application (Exhibits D-H) and the Office maintains that the subject matter of the present application and that of the parent application were directed to the same independent claim. The inventor to be deleted, Donald E. Inger, has disclaimed his inventorship in the parent application (Exhibit C) and the assignees have affirmed these corrections to inventorship in the parent application as well (Exhibits I and J). Applicants submit that the Declarations and Requests to Correct Inventorship (Exhibits A-K) originally applied to the claimed invention of the parent application (Mikos '608) are also applicable to the claimed invention of the present application. In light of these facts, please correct the inventorship of the present application by adding Linda G. Griffith and Georgios

Sarakinos as inventors and by excluding Donald E. Ingber as an inventor in the present application, so that the corrective entity of the present application is "Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith, and Georgios Sarakinos" as indicated in the application as filed.

If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date:

Clark & Elbing LLP 101 Federal Street

Boston, MA 02110

Telephone: 617-428-0200 Facsimile: 617-428-7045

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4

# DEC 1 9 2006

#### Exhibit A

PATENT ATTORNEY DOCKET NO. 01997/518003

Certificate of Mailing: Date of Deposit: June 7, 2002

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Prancis Parille

Printed name of person mailing correspondence

Signature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Antonios G. Mikos et al.

Art Unit:

1651

Serial No.:

09/669,760

Examiner:

D.M. Naff

Filed:

September 26, 2000

Customer No.:

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR

CELL TRANSPLANTATION.

Assistant Commissioner For Patents Washington, D.C. 20231

# REQUEST TO CORRECT INVENTORSHIPS -- DECLARATION OF INVENTOR ADDED

- I, Georgios Sarakinos, hereby declare:
- 1. That I am an original inventor in the above-referenced patent application.
- 2. That through error and without any deceptive intent on my part, the above-referenced application was filed naming "Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacanti" rather than "Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and Georgios Sarakinos".
  - 3. That I should be added as an inventor in the above-referenced application.

- 3. That I should be added as an inventor in the above-referenced application.
- 4. That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 24 May 2002

Georgios Sarakinos Keizer Karelplein 14 6211 TC Maastricht The Netherlands

\\Clark-w2k1\documents\01997\01997.518003 Decl. of Inv. to be added - GS.wpd



#### **Exhibit B**

/ PATENT ATTORNEY DOCKET NO. 01997/518003

Certificate of Mailing: Date of Deposit: June 7, 2002

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Commissioner for Patents, Washington, D.C. 20231.

Printed name of person mailing correspondence

Signature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Antonios G. Mikos et al.

Art Unit:

1651

Serial No.:

09/669,760

Examiner:

D.M. Naff

Filed:

September 26, 2000

Customer No.:

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR

CELL TRANSPLANTATION

Assistant Commissioner For Patents Washington, D.C. 20231

# REQUEST TO CORRECT INVENTORSHIPS -- DECLARATION OF INVENTOR ADDED

- I, Linda G. Griffith, hereby declare:
- 1. That I am an original inventor in the above-referenced patent application.
- 2. That through error and without any deceptive intent on my part, the above-referenced application was filed naming "Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacanti" rather than "Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and Georgios Sarakinos".
  - 3. That I should be added as an inventor in the above-referenced application.

4. That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 4 June 2002

Linda G. Griffith (formerly Linda G. Cima)

110 Antifrim Street Cambridge, MA 02139

\\Clark-w2k1\documents\01997\01997.518003 Decl. of Inv. to be added - LG.wpd

# DEC 19 2006

#### **Exhibit C**

PATENT ATTORNEY DOCKET NO. 01997/518003

Certificate of Mailing: Date of Deposit: Tun 7, 2002

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Rosimarie Penillo

Printed name of person mailing correspondence

Signature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Antonios G. Mikos et al.

Art Unit:

1651

Serial No.:

09/669,760

Examiner:

D.M. Naff

Filed:

September 26, 2000

Customer No.:

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR

**CELL TRANSPLANTATION** 

Assistant Commissioner For Patents Washington, D.C. 20231

# REQUEST TO CORRECT INVENTORSHIPS -- DECLARATION OF INVENTOR DELETED

- I, Donald Ingber, hereby declare:
- 1. That I am named as an original inventor in the above-referenced patent application.
- 2. That through error and without any deceptive intent on my part, the above-referenced application was filed naming "Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacanti" rather than "Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and Georgios Sarakinos".

- 3. That I should be deleted as an inventor in the above-referenced application.
- 4. That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 5/20/01

Donald E. Ingber

71 Montgomery Street Boston, MA 02116

\Clark-w2k1\documents\01997\01997.518003 Decl. to Cor. - delete invent. DI.wpd

#### **Exhibit D**

PATENT ATTORNEY DOCKET NO. 01997/518003

Certificate of Mailing: Date of Deposit June 7, 2002

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Rosemade Pavillo

Printed name of person mailing correspondence

Signature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Antonios G. Mikos et al.

Art Unit:

1651

Serial No.:

09/669,760

Examiner:

David M. Naff

Filed:

September 26, 2000

Customer No.

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERALS FOR CELL

TRANSPLANTATION

Assistant Commissioner of Patents and Trademarks Washington, DC 20231

# DECLARATIONS OF ANTONIOS G. MIKOS, Sc.D., ROBERT S. LANGER, Sc.D., LINDA G. GRIFFITH, Ph.D., and GEORGIOS SARAKINOS, Ph.D.

#### We declare:

- 1. We are inventors of the subject matter described and claimed in the abovecaptioned patent application.
- 2. We are inventors of the subject matter disclosed, but not claimed, in U.S.S.N. 08/012,270, now issued U.S. Patent No. 5,514,378.
- 3. At the time of invention of the subject matter described and claimed in the above-captioned patent application and invention of the claimed subject matter of U.S. Patent No. 5,514,378, we, Antonios Mikos, Robert Langer, Linda Griffith, and Georgios

Sarakinos, had an obligation to assign our rights to Massachusetts Institute of Technology.

4. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 6/6/02

Antonios G. Mikos, Sc.D.



## **Exhibit E**

PATENT ATTORNEY DOCKET NO. 01997/518003

Certificate of Mailing: Date of Deposit: June 7, 2002

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Commissioner of Patents, Washington, D.C. 20231.

Printed name of person mailing correspondence

Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Antonios G. Mikos et al.

Art Unit:

1651

Serial No.:

09/669,760

Examiner:

David M. Naff

Filed:

September 26, 2000

Customer No.

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERALS FOR CELL

TRANSPLANTATION

Assistant Commissioner of Patents and Trademarks Washington, DC 20231

# DECLARATIONS OF ANTONIOS G. MIKOS, Sc.D., ROBERT S. LANGER, Sc.D., LINDA G. GRIFFITH, Ph.D., and GEORGIOS SARAKINOS, Ph.D.

#### We declare:

- 1. We are inventors of the subject matter described and claimed in the abovecaptioned patent application.
- 2. We are inventors of the subject matter disclosed, but not claimed, in U.S.S.N. 08/012,270, now issued U.S. Patent No. 5,514,378.
- At the time of invention of the subject matter described and claimed in the . 3. above-captioned patent application and invention of the claimed subject matter of U.S. Patent No. 5,514,378, we, Antonios Mikos, Robert Langer, Linda Griffith, and Georgios

Sarakinos, had an obligation to assign our rights to Massachusetts Institute of Technology.

4. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

| Deter | 5/28/02 | MIN                   |
|-------|---------|-----------------------|
| Date: |         | Robert S'Langer Sc.D. |

DEC 19 2006

#### **Exhibit F**

ATTORNEY DOCKET NO. 01997/518003

Certificate of Mailing: Date of Deposit: June 7, 200Z

I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231.

Losemare Perullo
Printed name of person mailing correspondence

Sygnature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Antonios G. Mikos et al.

Art Unit:

1651

Serial No.:

09/669,760

Examiner:

David M. Naff

Filed:

September 26, 2000

Customer No.

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERALS FOR CELL

TRANSPLANTATION

Assistant Commissioner of Patents and Trademarks Washington, DC 20231

# DECLARATIONS OF ANTONIOS G. MIKOS, Sc.D., ROBERT S. LANGER, Sc.D., LINDA G. GRIFFITH, Ph.D., and GEORGIOS SARAKINOS, Ph.D.

#### We declare:

- 1. We are inventors of the subject matter described and claimed in the abovecaptioned patent application.
- 2. We are inventors of the subject matter disclosed, but not claimed, in U.S.S.N. 08/012,270, now issued U.S. Patent No. 5,514,378.
- 3. At the time of invention of the subject matter described and claimed in the above-captioned patent application and invention of the claimed subject matter of U.S. Patent No. 5,514,378, we, Antonios Mikos, Robert Langer, Linda Griffith, and Georgios

Sarakinos, had an obligation to assign our rights to Massachusetts Institute of Technology.

4. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 4 June 2002

Linda G. Griffith, Ph.D. (formerly Linda G. Cima)

### Exhibit G



ATTORNEY DOCKET NO. 01997/518003

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Losemade Kerullo

Printed name of person mailing correspondence

Signature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Antonios G. Mikos et al.

Art Unit:

1651

Serial No.:

09/669,760

Examiner:

David M. Naff

Filed:

September 26, 2000

Customer No.

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERALS FOR CELL

**TRANSPLANTATION** 

Assistant Commissioner of Patents and Trademarks Washington, DC 20231

# DECLARATIONS OF ANTONIOS G. MIKOS, Sc.D., ROBERT S. LANGER, Sc.D., LINDA G. GRIFFITH, Ph.D., and GEORGIOS SARAKINOS, Ph.D.

#### We declare:

- 1. We are inventors of the subject matter described and claimed in the abovecaptioned patent application.
- 2. We are inventors of the subject matter disclosed, but not claimed, in U.S.S.N. 08/012,270, now issued U.S. Patent No. 5,514,378.
- 3. At the time of invention of the subject matter described and claimed in the above-captioned patent application and invention of the claimed subject matter of U.S. Patent No. 5,514,378, we, Antonios Mikos, Robert Langer, Linda Griffith, and Georgios

Sarakinos, had an obligation to assign our rights to Massachusetts Institute of Technology.

4. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

| Date: | 24 | Man | 2002 |  |
|-------|----|-----|------|--|
|       |    |     |      |  |

Georgios Sarakinos, Ph.D.



#### Exhibit H

PATENT ATTORNEY DOCKET NO. 01997/518003

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I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231.

Kosemarie Herullo

Printed name of person mailing correspondence

nature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Antonios G. Mikos et al.

Art Unit:

1651

Serial No.:

09/669,760

Examiner:

David M. Naff

Filed:

September 26, 2000

Customer No.

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERALS FOR CELL

TRANSPLANTATION

Assistant Commissioner of Patents and Trademarks Washington, DC 20231

#### DECLARATION OF JOSEPH P. VACANTI, M.D.

#### I declare:

- 1. I am an inventor of the subject matter described and claimed in the abovecaptioned patent application.
- 2. I am an inventor of the subject matter disclosed, but not claimed, in U.S.S.N. 08/012,270, now issued U.S. Patent No. 5,514,378.
- 3. At the time of invention of the subject matter described and claimed in the above-captioned patent application and invention of the claimed subject matter of U.S. Patent No. 5,514,378, I, Joseph Vacanti, had an obligation to assign my rights to Children's Medical Center Corporation.

4. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

| Date: | 5/20/01 | JRH-                    |
|-------|---------|-------------------------|
|       |         | Joseph P. Vacanti, M.D. |



#### **Exhibit I**

ATTORNEY DOCKET NO. 01997/518003

Certificate of Mailing: Date of Deposit June 7, 2002

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Commissioner for Patents, Washington, D.C. 20231.

Printed name of person mailing correspondence

Signature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Antonios G. Mikos et al.

Art Unit:

1651

Serial No.:

09/669,760

Examiner:

D.M. Naff

Filed:

September 26, 2000

Customer No.:

21559

Title:

to:

POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR

CELL TRANSPLANTATION

Assistant Commissioner For Patents Washington, D.C. 20231

#### REOUEST TO CORRECT INVENTORSHIP -- CONSENT OF ASSIGNEE

As an officer of the concern to which the above captioned application has been assigned, I hereby consent to the correction of inventorship of this application from:

--Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacanti--

"Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and Georgios Sarakinos".

All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements

are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

21 May 2002

Donald P. Lombardi

Chief Intellectual Property Officer The Children's Medical Center Corp. 300 Longwood Avenue

Boston, MA 02115

\\Clark-w2k1\documents\01997\01997.518003 Dec of Inv. Consent of Assignee - Childrens.wpd

DEC 19 2006 &





ATTORNEY DOCKET NO. 01997/518003

Certificate of Mailing: Date of Deposit: June 7, 2002

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Yerullo asemane

Printed name of person mailing correspondence

Signature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Antonios G. Mikos et al. Art Unit:

1651

Serial No.:

09/669,760

Examiner:

D.M. Naff

Filed:

September 26, 2000

Customer No.:

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR

CELL TRANSPLANTATION

Assistant Commissioner For Patents Washington, D.C. 20231

#### REQUEST TO CORRECT INVENTORSHIP -- CONSENT OF ASSIGNEE

As an officer of the concern to which the above captioned application has been assigned, I hereby consent to the correction of inventorship of this application from: -- Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacantito:

"Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and Georgios Sarakinos".

All statements made herein of my own knowledge are true and that all statements

made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 6/5/02

Rita Filopowicz

Patent Administrator

Massachusetts Institute of Technology

77 Massachusetts Avenue

Cambridge, MA 02139-4307

\CLARK-W2K1\documents\01997\01997.518003 Dec of lnv. Consent of Assignee.wpd

#### Exhibit K

**PATENT** 

#### **ATTORNEY DOCKET NO. 01997/518003**

Certificate of Mailing: Date of Deposit: \_\_June 7, 2002

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Rosemarie Perullo

Printed name of person mailing correspondence

Signature of person mailing correspondence

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Antonios G. Mikos et al.

Art Unit:

1651

Serial No.:

09/669,760

Examiner:

David M. Naff

Filed:

September 26, 2000

Customer No.:

21559

Title:

POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL

TRANSPLANTATION

Assistant Commissioner for Patents Washington, D.C. 20231

#### REQUEST TO CORRECT INVENTORSHIP UNDER 37 CFR §1.48 (a)

Applicant hereby requests correction of inventorship in the above-referenced application

from:

-- Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacanti--

to:

"Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and Georgios Sarakinos".

The inventors set forth in the executed declaration under 37 C.F.R. § 1.63 filed January 23, 2001 were in error. In support of this request, enclosed are the following:

- ☑ A statement from each person being <u>added</u> as an inventor, executed by Linda G. Griffith and Georgios Sarakinos.
- ☑ A statement from each person being deleted as an inventor, executed by Donald Ingber.

☑ A newly executed Combined Declaration and Power of Attorney by Linda G. Griffith and Georgios Sarakinos.

■ A consent of the assignee to this correction of inventorship executed by Rita Filipowicz and Donald Lombardi.

☑ A check for \$130.00 for the fee required under 37 C.F.R. § 1.17(i).

If there are any other charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: June 7, WOZ

ristina/Bieker-Brady, Ph.D

/Reg. No. 39,109<sup>(</sup>

Clark & Elbing LLP 101 Federal Street Boston, MA 02110

Telephone: 617-428-0200

Facsimile: 617-428-7045

21559

PATENT TRADEMARK OFFICE

\\Clark-w2k1\documents\01997\01997.518003 Req. Correct Invt. 1.48(a).wpd

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

| inventor (if plural names a invention entitled:                                 | re listed below) of the  | inventor (if only one name is listed belo<br>subject matter which is claimed and for<br>DABLE POLYMERIC MATERIALS<br>ANTATION   | w), or an original, first and joint which a patent is sought on the  |
|---|--|---|--|
| the specification of which (  | check one)   |   | <u> </u>   |
|   |  | is attached hereto  |  |
|   |  | X was filed on April 23, 19   | 93   |
|   |  | as application Serial No. 08/0  | 522,387  |
|   | į  | and was amended on:   | P. Alax  |
|   |  | (if app   | ncable)  |
| I hereby state that claims, as amended by any                                   | I have reviewed and amendment referred   | understand the contents of the above-ide to above.  | entified specification, including the  |
| I acknowledge the accordance with Title 37,                                     | duty to disclose inform<br>Code of Federal Regul   | nation which is material to the examina ations, § 1.56(a).  | tion of this application in  |
| natent or inventor's certifi  | cate listed below and l<br>late before that of the   | under Title 35, United States Code, § 11 have also identified below any foreign application on which priority is claimed  | pplication for patent or inventor's  |
| (Number)  | (Country)  | (Day/Month/Year Fi  | led)   |
| (Number)  | (Country)  | (Day/Month/Year Fi  | led)   |
| (Number)  | (Country)  | (Day/Month/Year Fi  | led)   |
| below and, insofar as the application in the manner to disclose material inform | subject matter of each provided by the first nation as defined in Tiplication and the nation part 18/012,270 | 5, United States Code, § 120 of any United States of the application is not of paragraph of Title 35, United States Cottle 37, Code of Federal Regulations, § nal or PCT international filing date of February 1, 1993  (Filing Date) | disclosed in the prior United States<br>ide, § 112, I acknowledge the duty<br>1.56(a) which occurred between the |
| (Application Serial No.   | )  | (Filing Date)   | Status (natented, pending, abandoned   |

"Porous Biodegradabl Polymeric Materials for Con Transplantation" By: Antonios G. Mik , et al. Filed: April 23, 1993

DECLARATION

As named inventor, I hereby appoint the following attorney(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

| John S. Pratt      | 29,476 |
|--------------------|--------|
| James L. Ewing, IV | 30.630 |
| Patrea L. Pabst    | 31,284 |
| Jamie L. Greene    | 32,467 |
| Cheryl K. Zalesky  | 33,052 |
| Dean W. Russell    | 33,452 |
| Claudia R. Adkison | 36,979 |
| Charles T. Simmons | 35.359 |

Send Correspondence to:

Patrea L. Pabst, Esq. Kilpatrick & Cody

1160 Peachtree Street, Suite 2800 Atlanta, Georgia 30309-4530

Direct telephone calls to:

Patrea L. Pabst (404)815-6508, or John S. Pratt (404)815-6367

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any natent issued thereon.

| patent issued thereon.  |
|---|
| Full name of sole or first inventor Antonios G. Mikos           |
| Inventor's signature Date                                       |
| Residence 4100 Greenbriar Drive, Apt. 345, Houston, Texas 77098 |
| Citizenship Greece  |
| Post Office Address Same as above                               |
|   |
| Full name of second joint inventor (if any) Donald E. Ingber    |
| Inventor's signature  |
| Residence 71 Montgomery Street, Boston, Massachusetts 02116     |
| CitizenshipUnited States  |
| Post Office Address Same as above                               |
|   |

| Porous Biodegradable olymeric Materials  for Cell Transplants on                                     |                                       |
|--|---------------------------------------|
| ay. Antonios G. Mikos, et al.  |                                       |
| TICLE APATION joint inventor (if any) Joseph A. Vacanti  |                                       |
| riled: April 23, 1993  Company Joseph F. Vacanti  Inventor's signature Old Company Joseph F. Vacanti | Date <u>5/8/93</u>                    |
| Residence 14 Woodside Road, Winchester, Massachusetts 01890  |                                       |
| CitizenshipUnited States   | · · · · · · · · · · · · · · · · · · · |
| Post Office Address Same as above  |                                       |
|  |                                       |
|  |                                       |
| Full name of fourth joint inventor (if any)Robert S. Langer  |                                       |
| Inventor's signature   |                                       |
| Residence 77 Lombard Street, Newton, Massachusetts 02158   |                                       |
| CitizenshipUnited States   |                                       |
| Post Office Address Same as above  |                                       |
|  |                                       |
|  |                                       |
| Full name of fifth joint inventor (if any)   |                                       |
| Inventor's signature   |                                       |
| Residence  |                                       |
| Citizenship  |                                       |
| Post Office Address  |                                       |
|  |                                       |
| Full name of sixth joint inventor (if any)   |                                       |
|  | _                                     |
| Inventor's signature   |                                       |
| Residence  |                                       |
| Citizenship  |                                       |
| Post Office Address  |                                       |

"Porous Biodegradable olymeric Materials for Cel Pransplantation" By: Antonios G. Mike et al. Filed: April 23, 1993 DECLARATION

As named inventor, I hereby appoint the following attorney(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

| John S. Pratt      | 29,476 |
|--------------------|--------|
| James L. Ewing, IV | 30,630 |
| Patrea L. Pabst    | 31,284 |
| Jamie L. Greene    | 32,467 |
| Cheryl K. Zalesky  | 33,052 |
| Dean W. Russell    | 33,452 |
| Claudia R. Adkison | 36,979 |
| Charles T. Simmons | 35,359 |

Send Correspondence to:

Patrea L. Pabst, Esq. Kilpatrick & Cody

1100 Peachtree Street, Suite 2800 Atlanta, Georgia 30309-4530

Direct telephone calls to:

Patrea L. Pabst (404)815-6508, or John S. Pratt (404)815-6367

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

| Full name of sole or first inventor Antonios G. Mikos          |        |                 | <del></del> |
|--|--------|-----------------|-------------|
| Inventor's signature   | Date_  | May             | 13 1        |
| Residence 4100 Greenbriar Drive, Apt. 345, Houston, Texas 7709 | 98     | ··············· | <del></del> |
| Citizenship Greece   |        |                 |             |
| Post Office Address Same as above                              |        |                 |             |
|  | ·      |                 |             |
| Full name of second joint inventor (if any) Donald E. Ingber   |        |                 |             |
| Inventor's signature   | _ Date |                 | <del></del> |
| Residence71 Montgomery Street, Boston, Massachusetts 02116     |        |                 |             |
| CitizenshipUnited States                                       |        |                 |             |
| Post Office Address Same as above                              |        |                 |             |
|  |        |                 |             |

| "Porous Biodegrada : Polymeric Materials for Cell Transplation" By: Antonios G. Minos, et al. Piled: April 23, 1993 DECLARATION joint inventor (Many) Joseph H. Vacanti |              |
|---|--------------|
| Inventor's signature 6417.  | Date 5/8/93  |
| Residence 14 Woodside Road, Winchester, Massachusetts 0   |              |
| Clitzenship United States   |              |
| Post Office Address Same as above   |              |
|   |              |
| Full name of fourth joint inventor (if any) Robert S. Langer  | Date 6 16 93 |
| Inventor's signature  | 1 1          |
| Residence 77 Dombard Street, Newton, Massachusetts 02:32  |              |
| Post Office Address Same as above   | •            |
| Post Office Address   |              |
| ·   |              |
| Full name of fifth joint inventor (If any)  |              |
| Inventor's signature  | Date         |
| Residence   |              |
| Citizens hip  |              |
| Post Office Address   |              |
|   |              |
| Full name of sixth joint inventor (if any)  |              |
| Inventor's signature  | Date         |
| Residence   |              |
| Citizenship   |              |
| Post Office Address   |              |
|   |              |
| ·   |              |
|   |              |
|   |              |
| <b>3-</b>   |              |
|   |              |
|   |              |

ţ

#### Exhibit M



21559

#### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Yingina 22313-1450 www.unjungov

APPLICATION NUMBER

FILING OR 371 (c) DATE

FIRST NAMED APPLICANT

ATTORNEY DOCKET NUMBER

10/775,768

**CLARK & ELBING LLP** 

**BOSTON, MA 02110** 

101 FEDERAL STREET

02/10/2004

Antonios G. Mikos

01997/518004

**CONFIRMATION NO. 8716** 

**FORMALITIES LETTER** 

\*OC000000012556104\*

Date Mailed: 05/06/2004

#### NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

#### **Items Required To Avoid Abandonment:**

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing. Applicant must submit \$ 385 to complete the basic filing fee for a small entity.
- The oath or declaration is missing. A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

#### **SUMMARY OF FEES DUE:**

Total additional fee(s) required for this application is \$450 for a Small Entity

- \$385 Statutory basic filing fee.
- \$65 Late oath or declaration Surcharge.

Replies should be mailed to:

Mail Stop Missing Parts

Commissioner for Patents

P.O. Box 1450

Alexandria VA 22313-1450

### A copy of this notice MUST be returned with the reply.

Initial Patent Examination Division (703) 308-1202
PART 2 - COPY TO BE RETURNED WITH RESPONSE

#### **Exhibit N**

| Certificate | of | Mai | ling |
|-------------|----|-----|------|
|-------------|----|-----|------|

Date of Deposit: February 10, 2004

Label Number: EV 232035151 US

I hereby certify under 37 C.F.R. § 1.10 that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" with sufficient postage on the date indicated above and is addressed to Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Elvis De La Cruz

Printed name of person mailing correspondence

Signature of person mailing correspondence

#### **APPLICATION**

#### **FOR**

#### UNITED STATES LETTERS PATENT

**APPLICANT** 

ANTONIOS G. MIKOS, ROBERT S. LANGER, JOSEPH P.

VACANTI, LINDA G. GRIFFITH AND GEORGIOS

**SARAKINOS** 

TITLE

POROUS BIODEGRADABLE POLYMERIC MATERIALS

FOR CELL TRANSPLANTATION

#### **Exhibit O**



#### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Vignia 22313-1450 www.unite.com

| APPL NO.   | FILING OR 371<br>(c) DATE | ART UNIT | FIL FEE REC'D | ATTY DOCKET NO | DRAWINGS | TOT CLMS | IND CLMS |
|------------|---------------------------|----------|---------------|----------------|----------|----------|----------|
| 10/775,768 | 02/10/2004                | 1651 .   | 450           | 01997/518004   | 5.       | 3        | 1        |

**CONFIRMATION NO. 8716** 

**UPDATED FILING RECEIPT** 

\*OC00000018325270\*

21559 CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110

Docksting Required

Date Mailed: 03/21/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

#### Applicant(s)

Antonios G. Mikos, Houston, TX; Donald E. Ingber, Boston, MA; Joseph P. Vacanti, Winchester, MA; Robert S. Langer, Newton, MA; RECE

MAR 2 8 2006

CLARK & L.

#### **Power of Attorney:**

Paul Clark-30162 Karen Elbing-35238 Mary Scozzafava-36268 Kristina Bieker-Brady-39109 Sean Edman-42506 Susan Michaud-42885 James DeCamp-43580

#### Domestic Priority data as claimed by applicant

This application is a CON of 08/669,760 06/26/1996 PAT 5,610,753 \* which is a CON of 08/052,387 04/23/1993 ABN which is a CIP of 08/012,270 02/01/1993 PAT 5,514,378 (\*)Data provided by applicant is not consistent with PTO records.

#### Foreign Applications

If Required, Foreign Filing License Granted: 05/06/2004

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US10/775,768

**Projected Publication Date:** 06/29/2006

Non-Publication Request: No

Early Publication Request: No

\*\* SMALL ENTITY \*\*

Title

Porous biodegradable polymeric materials for cell transplantation

**Preliminary Class** 

435

#### PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

**GRANTED** 

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### **NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



#### United States Patent and Trademark Office

### **Exhibit P**

www.uspto.gov

| APPLICATION NO.           | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---------------------------|----------------|----------------------|-------------------------|------------------|
| 10/775,768                | 02/10/2004     | Antonios G. Mikos    | 01997/518004            | 8716             |
| 21559 7.                  | 590 06/29/2006 |                      | EXAM                    | INER             |
| CLARK & EI                |                |                      | NAFF, DA                | AVID M           |
| 101 FEDERAL<br>BOSTON, MA |                |                      | ART UNIT                | PAPER NUMBER     |
|                           | I              | RECEIVED             | 1651                    |                  |
|                           | Ę.             | the Vani Vani        | DATE MAILED: 06/29/2006 | 5                |
|                           |                | JUL 0 3 2005         | ·                       |                  |
|                           | CL             | ARK & ELBING LLP     |                         |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

DUE DATE 9.29.06
ESP 12.29.06
INITIALS TM

|  |  | Application No.  | Applicant(s)  |
|--|--|--|---|
|  |  | 10/775,768   | MIKOS ET AL.  |
|  | Office Action Summary  | Examiner   | Art Unit  |
|  |  | David M. Naff  | 1651  |
|  | The MAILING DATE of this communication app   | pears on the cover sheet v   | vith the correspondence address   |
| Period fo  | • •  |  | ACAITH (CO.) OR THERE (CO.) DAYO  |
| WHIC<br>- Exte<br>after<br>- If NC<br>- Failu<br>Any | ORTENED STATUTORY PERIOD FOR REPL' CHEVER IS LONGER, FROM THE MAILING Donsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Depriod for reply is specified above, the maximum statutory period of the provision of the provi | ATE OF THIS COMMUN 36(a). In no event, however, may a will apply and will expire SIX (6) MC accuse the application to become A | ICATION.  reply be timely filed  INTHS from the mailing date of this communication.  ABANDONED (35 U.S.C. § 133). |
| Status   |  |  |   |
| 1)⊠  | Responsive to communication(s) filed on 10 F   | <u>ebruary 2004</u> .  |   |
| ,—   | ·—·  | action is non-final.   |   |
| 3)   | Since this application is in condition for allowa  |  |   |
|  | closed in accordance with the practice under E   | ±x parte Quayle, 1935 €.   | D. 11, 453 O.G. 213.  |
| Disposit   | ion of Claims  |  |   |
| 4)🖂  | Claim(s) 11-13 is/are pending in the application   | n.   |   |
|  | 4a) Of the above claim(s) is/are withdra   | wn from consideration.   |   |
| ′=   | Claim(s) is/are allowed.   |  |   |
|  | Claim(s) <u>11-13</u> is/are rejected.   |  |   |
|  | Claim(s) is/are objected to.  Claim(s) are subject to restriction and/o  | or election requirement  |   |
| الــا(ه  | Claim(s) are subject to restriction and/c  | or election requirement.   |   |
| Applicat   | ion Papers   |  |   |
| ,  | The specification is objected to by the Examine  |  |   |
| 10)⊠   | The drawing(s) filed on 10 February 2004 is/ar   |  |   |
|  | Applicant may not request that any objection to the  |  |   |
| 11)  | Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex  |  |   |
| -  |  | Nammer. Note the attack  | 54 CHICC / GUOTI OF TOTAL TO 152.   |
| Priority   | under 35 U.S.C. § 119  |  |   |
|  | Acknowledgment is made of a claim for foreign  | priority under 35 U.S.C.   | § 119(a)-(d) or (f).  |
| a)   | □ All b)□ Some * c)□ None of:  |  |   |
|  | 1. Certified copies of the priority document   |  | Analization No.   |
|  | <ul><li>2. Certified copies of the priority document</li><li>3. Copies of the certified copies of the priority</li></ul>   |  |   |
|  | application from the International Burea   |  | Il received in this Ivational Stage   |
| *  | See the attached detailed Office action for a list   | •  | ot received.  |
|  |  | ·  |   |
| Attachme   |  | <b>∧</b> □ 1-4 *   | Summan (DTO 412)  |
|  | ice of References Cited (PTO-892) ice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No   | Summary (PTO-413)<br>p(s)/Mail Date   |
| 3) X Info  | rmation Disclosure Statement(s) (PTO-1449 or PTO/SB/08 er No(s)/Mail Date 6/23/05.   | ) 5) ☐ Notice of 6) ☐ Other: _   | Informal Patent Application (PTO-152)   |

Art Unit: 1651

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#### DETAILED ACTION

A preliminary amendment of 2/10/04 canceled claims 1-10, and added new claims 11-13.

A preliminary amendment of 6/14/04 amended the specification.

Claims examined on the merits are 11-13, which are all claims in the application.

#### Specification

The disclosure is objected to because of the following informalities: this application cannot be a continuation of parent application 09/669,760 as stated in the first paragraph of the specification since this application has a different inventive entity from the parent application. An inventorship change should be made in this application as in the parent application. Furthermore, this application cannot be continuation of parent application 08/052,387 unless the inventorship change in 09/669,760 was also made in 08/052,387.

Appropriate correction is required.

It is noted that the Vacanti et al (Journal of Pediatric Surgery) listed on form 1449 has a publication date of Jan 98. However, patent 5,514,378 gives the date as 1988. Which is correct?

#### Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In

Art Unit: 1651

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re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 11 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,689,608 B1. This is a double patenting rejection.

Claim 11 is identical to that of claim 1 of the patent.

#### Double Patenting

The nonstatutory double patenting rejection is based on a 15 judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the 20 conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In 25 re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). 30

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

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Art Unit: 1651

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7 of U.S. Patent No. 6,689,608 B1 in view of Vacanti et al (5,759,830).

The polymeric matrix of the claims of the patent is the same as presently claimed except for matrix comprising cells as required by claim 12 and comprising a material enhancing cell attachment as required by claim 13.

Vacanti et al disclose attaching cells to a polymeric matrix.

Different types of cells can be attached (col 6, lines 27-34), and the matrix can be coated with a coating that enhances cell attachment (col 10, lines 43-48).

Since the matrix of the patent claims is required by the claims to be suitable for attachment and proliferation of cells, it would have been obvious to attach to the matrix of the patent claims cells disclosed by Vacanti et al for attaching to a matrix. It would have been further obvious to coat the matrix of the patent claims with a cell attachment enhancing coating as disclosed by Vacanti et al to obtain the attachment enhancing function of the coating.

#### Double Patenting

Claim 11 is rejected on the ground of nonstatutory obviousnesstype double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,514,378. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent require a method for producing a porous biocompatible synthetic polymer membrane wherein crystallinity is modified (claim 2), the membrane has a porosity of greater than 90%

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(claim 9), and particles are used that will produce a pore size of 100-500 microns (claim 4). When modifying the crystallinity as claimed by claim 2 of the patent, it would have been obvious to select a preferred optimum degree of crystallinity of 0-24.5% as presently claimed. A membrane from the method of the patent claims having this crystallinity will be a matrix that is the same as the presently claimed matrix.

#### Double Patenting

Claims 12 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,514,378 in view of Vacanti et al (5,759,830).

It would have been obvious to attach cells to the membrane resulting from the process of the patent claims to obtain the function of cells attached to the membrane as suggested by Vacanti et al when attaching cells to a matrix since the membrane resulting from the method of the patent claims is biocompatible. Vacanti et al would have further suggested coating the membrane with a cell attachment enhancing coating as required by claim 13 to enhance cell attachment.

The patents listed on form PTO-892 other than applied are patents made of record in parent application 09/669,760.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff Primary Examiner Art Unit 1651

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\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



Attorney Docket No. 01997/518004 U.S. DEPARTMENT OF COMMERCE SUBSTITUTE FORM PTO-1449 PATENT AND TRADEMARK OFFICE (MODIFIED) Serial No. 10/775,768 Applicant Antonios G. Mikos et al. INFORMATION DISCLOSURE Filing Date February 10, 2004 STATEMENT BY APPLICANT (Use several sheets if necessary) 1651 Group June 21, 2005 **IDS Filed** (37 C.F.R. § 1.98(b)) U.S. PATENT DOCUMENTS Filing Date Subclass Class Patentee or Applicant Examiner's Document Issue or (If Appropriate) **Publication** Number Initials Date 178 4,352,883 10/82 Lim 4,458,678 7/84 Yannas et al. Reli 11/84 4,485,097 Aivasidis et al. 5,096,814 03/92 08/91 Vacanti et al. 5,041,138 07/89 Grande 11 4,846,835 Urist 4,563,489 01/86 11/77 Yannas et al. 15 4,060,081 4,391,909 01/83 Schmidt et al. 4,520,821 06/85 4,897,267 01/90 Bontempts et al. Om. Toyomoto et al. 5,064,866 11/91 FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS Translation Country or Subclass Publication Examiner's Document Patent Office (Yes/No) Date Number Initials 01/1989 Japan 1268733 678407 09/1991 Switzerland 11/1990 WIPO 9072604 OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) Vacanti et al., Journal of Pediatric Surgery 23:3-9 (Jan 98) Vacanti, Arch. Surg., 123:545-549 (1998) DATE CONSIDERED 06 EXAMINER EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.